



## UNITED STATES PATENT AND TRADEMARK OFFICE

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UNITED STATES PATENT AND TRADEMARK OFFICE  
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APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/811,824	03/20/2001	George P. Anderson	01997-282001 / MIT Case 8

CONFIRMATION NO. 8422

## FORMALITIES LETTER



\*OC000000006414729\*

ERIC L. PRAHL  
Fish & Richardson P.C.  
225 Franklin Street  
Boston, MA 02110-2804

Date Mailed: 08/13/2001

### NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant is given **TWO MONTHS FROM THE DATE OF THIS NOTICE** within which to file the items indicated below to avoid abandonment. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (703) 308-4216
- To Purchase PatentIn Software, call (703) 306-2600
- For PatentIn Software Program Help, call (703) 306-4119 or e-mail at [patin21help@uspto.gov](mailto:patin21help@uspto.gov) or [patin3help@uspto.gov](mailto:patin3help@uspto.gov)

*A copy of this notice **MUST** be returned with the reply.*

nlv

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Initial Patent Examination Division (703) 308-1202

PART 3 - OFFICE COPY



## UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
09/811,824	03/20/2001	George P. Anderson	01997-282001 / MIT Case 8

CONFIRMATION NO. 8422

## CORRECTION COVER LETTER



\*OC000000006414713\*

ERIC L. PRAHL  
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Boston, MA 02110-2804

Date Mailed: 08/13/2001

## COVER LETTER FOR CORRECTION OF PREVIOUS NOTICE

The Notice mailed on 07/30/2001 was sent in error and is hereby withdrawn. A corrected Notice is enclosed. The time period for reply runs from the mail date of the corrected Notice. We apologize for any inconvenience this caused.

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*A copy of this notice MUST be returned with the reply.*

*Na*  
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Initial Patent Examination Division (703) 308-1202

PART 3 - OFFICE COPY

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-56, drawn to the composition and method making same, classified in Class [3], subclass [4].
- II. Claims 57 and 58, drawn to a method of use of the composition, classified in Class [3], subclass [4].

To define the composition of Group I and method of use in Group II, applicant needs to elect under 35 USC 121:

- (a) an inorganic particle
- (b) a linking group with a proximal end with a charged/ionizable moiety
- (c) a macromolecule with charged moiety(ies)

Applicant is to elect one of each:

- One specific inorganic particle (see, e.g., claims 2, 10) and type of compound from claim 3;
- One specific linker (see e.g., claim 13)
- One specific ionizable/charged groups (see, e.g., claim 11)
- One specific macromolecule:
  - an inorganic macromolecule (specification page \_\_\_\_ indicates the macromolecule can be inorganic); or,
  - a polypeptide (claim 15); or,
  - a polynucleotide (claim 15)

As to inorganic macromolecule (which is not the same as inorganic particle), applicant is to elect one specific inorganic molecule disclosed;

As to polypeptide macromolecule, applicant is to elect between fusion protein (claim 21) and a nonfusion protein (claim 15), e.g., leucine zipper (claim 17). Polyaspartate (claim 18), maltose binding protein (claim 19), immunoglobulin G binding protein (claim 20)

The inventions are distinct, each from the other for the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the composition can be used in a therapeutic process, one of treatment of a disease state on the basis of the activity of the selected macromolecule.

As to the macromolecule, the inorganic macromolecule is not interchangeable with any of the polypeptides nor the polynucleotides; and, in addition, the polynucleotides are not a substitute for the polypeptides. As to the polypeptides, the maltose binding protein, e.g., is not an immunoglobulin binding protein.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

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Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

- 10    823 telephone election  
      8231 telephone nonelection  
      8232 joint inventors

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- 20        Inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Low whose telephone number is (703) 308-2923. Inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

- 25        Papers related to this application may be submitted by facsimile transmission to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1) and must conform to the notice published in the Official Gazette, 1096 OG 30 (15 November 1989). The telephone number assigned to Art Unit 1653 in the CM1 PTO Fax Center is (703) 308-4242 or 305-3014.

CSFL  
date

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S/N: 09811824

Docket No.:

Inventors:

Attorney:

Telephone:

Firm:

Address:

US Filing Date:

Continuing Data:

Foreign Priority Data:

Title:

Class/subclass:

Notes: